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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Alignment of SEQ ID NO: 11 with selected ESTs.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 3, directed to SEQ ID NO: 11 in the reply filed on 5/22/2006 is acknowledged. The traversal is on the ground(s) that that the restriction to a single sequence is improper as the Office has partially waived the requirements of 37 CFR 1.141. This is not found persuasive because the partial waiver stated that "up to ten" sequences may be searched. However, in the instant case, searching more than 1 of the structurally and functionally distinct sequences presents a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4) as well as consisting of SEQ ID NO: 11 (claim 5). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) or consisting (claim 7) of a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claims 3 and 5 do not allow for internal variations within SEQ ID NO: 11. Claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-2, 4, 6, and 8 allow for internal variations. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-

specific uses that are applicable to in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. For example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then

the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or

suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1-4, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claim 3 does not allow for internal variations within SEQ ID NO: 11. However, SEQ ID NO: 11 does not appear to be a full length open reading frame and therefore, claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-2, 4, 6 and 8 allow for internal variations within SEQ ID NO: 11. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches the sequence of SEQ ID NO: 11. SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. However, the specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and

provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first nucleotide in a codon, or the second or third. Accordingly, it is not even clear that SEQ ID NO: 11 encodes a protein (claim 2). Further, claim 2 specifically recites a nucleic acid which encodes a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids of claim 1 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims. Further, claims 1, 2, 4, 6, and 8 encompass sequences which possess variations with regard to the sequence of SEQ ID NO: 1, while claims 1-4, 6, and 8, due to the language "comprising" encompass a large genus of sequences which are larger than SEQ ID NO: 11. Although, for example, claim 3 encompasses a vector which comprises SEQ ID NO: 11, the claim also encompasses a full length cDNA, as well as genomic sequences, which have not been described by the specification. Such sequences include introns, exons, promoters, enhancers, 5' and 3' UTR's, all of which have not been described by the specification. Further, claims 1, 2, 4, 6, and 8 encompass allelic variants, mutants, and homologs of the undisclosed cDNA and genomic sequences. As such, each member of the claimed genus does not contain the same structural feature. This represent a large variable genus of nucleic acid molecules which are not represented by the single sequence of SEQ ID NO: 11. The specification does not disclose a single variant or homolog of SEQ ID NO: 11, nor any sequence with a "single nucleotide polymorphism". There is no structure function correlation between the

single disclosed species, and the large genus of genes, cDNAs, mutants, variants, and homologs encompassed by the broadly claimed invention.

In addition, claims which recite "comprising *a* nucleic acid sequence of SEQ ID NO: 11" and "comprising *a* nucleic acid sequence selected from the group of SEQ ID NO: 11" encompass sequences of any magnitude and/or content that comprise at least a minimum of a two base pair sequence of SEQ ID NO: 11. The claims encompass includes variants, homologs, and mutants of SEQ ID NO: 11, with either retained or altered function. EST Accession number which are encompassed by large variable genus include CG081396, BZ527744, CC627264, from Zea Mays EST's with no disclosed function, and CA203440, a Sacharum officinarum EST with no disclosed function (alignments provided). Each of these sequences comprise a number of nucleotide positions which align 100% with SEQ ID NO: 11. Beyond providing the sequence data for SEQ ID NO: 11, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 11 to its function, which amino acids in the protein encoded by SEQ ID NO: 11 are critical to its function, or how to modify SEQ ID NO: 11 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 11 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 11. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 11.

While one could argue that the claimed genus of polynucleotides is adequately described since one can identify these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's

function. For example, Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

The genus of polynucleotides comprised by the claims is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 11, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 1-4, 6, and 8.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO: 11, and the complete complement thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by products O3003 and O4378 of the 1991 SIGMA Chemical Catalog.

In the 1993 Sigma Chemical Catalog product O3628 is a 4-mer oligonucleotide of poly dT nucleotides and product O4378 is a 4-mer oligonucleotide of poly dA nucleotides, both of which are 100% identical to a nucleic acid sequence of SEQ ID NO: 11. It is noted that these oligonucleotides are at least about 95%-100% (and 99%-100%) identical to poly A segments or their complementary respective poly T segments of the instantly claimed nucleic acids. Further, the term "complements" has been broadly interpreted to encompass sequence which are completely complementary to fragments of SEQ ID NO: 11. The sequences of Sigma catalog, thus anticipate the claims via segments therein which are poly T segments or poly A segments present in the SEQ ID NO: 1. With respects to claim 8, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 8. Any sequence can potentially comprise a SNP and depends on what one is comparing it to. Therefore

the O3628 and O4378 products anticipate claims 1-8 as a nucleic acid molecule comprising or consisting of a nucleic acid sequence of SEQ ID NO: 1 or "complements" thereof.

10. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor (US Patent 6,582,908).

The term "complements" has been broadly interpreted to encompass sequence which are completely complementary to fragments of SEQ ID NO: 11. Fodor teaches an array of every possible 10 mer nucleic acid molecule. The claims encompass a genus of 10 mer nucleic acid sequences which are "complements" of SEQ ID NO: 11, as well as complements of sequences with the recited %identity to "a molecule comprising *a* nucleotide sequence having... % identity", and sequences "having a single nucleotide polymorphism, which are anticipated by the teachings of Fodor.

11. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Brennan (US Patent 5,474,796).

The term "complements" has been broadly interpreted to encompass sequence which are completely complementary to fragments of SEQ ID NO: 11. Fodor teaches an array of every possible tri-mer nucleic acid molecule (Figure 1). The claims encompass a genus of tri-mer nucleic acid sequences which are "complements" of SEQ ID NO: 11, as well as complements of sequences with the recited %identity to "a molecule comprising *a* nucleotide sequence having... % identity", and sequences "having a single nucleotide polymorphism, which are anticipated by the teachings of Brennan.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634

7/31/06